IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE

METHODIST HEALTHCARE MEMPHIS HOSPITALS, Plaintiff, v. XAVIER BECERRA, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	Case No. 2:21-cv-02476-JPM-atc

ORDER GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Before the Court is Plaintiff's Motion for Summary Judgment, filed on February 28, 2022. (ECF No. 21.) On April 15, 2022, Defendant filed an Opposition to Plaintiff's Motion for Summary Judgment. (ECF No. 25.) Plaintiff filed a Reply on May 5, 2022. (ECF No. 26.)

For the reasons discussed below, Plaintiff's Motion for Summary Judgment is hereby **GRANTED**.

I. BACKGROUND

A. Factual Background

a. Medicare and Post-Payment Audits

Plaintiff Methodist Healthcare – Memphis Hospitals ("Methodist") is a nonprofit "healthcare system" operating hospitals in the Memphis area. (ECF No. 21-1 at PageID 1683.) Defendant is the Secretary of the Department of Health and Human Services ("HHS"). (See ECF No. 25 at PageID 1715.) The Secretary of HSS administers the Medicare program, a federal health insurance program for elderly and disabled individuals, through the Centers for Medicare and

Medicaid Services ("CMS"). See 42 U.S.C. § 1395 et seq. The Medicare program generally issues payments to healthcare providers upfront. See Bertschland Family Practice Clinic, P.C. v. Thompson, No. IPO1-562-CH/F, 2002 WL 1364155, at *2 (S.D. Ind. June 4, 2002). Medicare contractors or other agents then conduct post-payment audits to ensure that those upfront payments "were made in accordance with applicable Medicare payment criteria." Gulfcoast Med. Supply, Inc. v. Sec'y, Dep't of Health and Human Servs., case No. 8:04-cv-2610-T-26EAJ, 2005 WL 3934860 at *2 (M.D. Fla. Nov. 16, 2005), aff'd 468 F.3d 1347 (11th Cir. 2006). Per a 1986 administrative ruling by CMS, statistical sampling may be used for these audits. See CMS Rul. 86-1, Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers (Feb. 20, 1986). CMS has issued a manual, the Medicare Program Integrity Manual ("MPIM"), with principles, guidelines, and directives for these audits, including guidance regarding statistical sampling methodology and overpayment extrapolation. See MPIM Ch. 8 § 8.4.1.3 (Pub. No. 100-08, Rev. 377) (2011). Audits may assess overpayments which healthcare providers must pay in order to safeguard Medicare funds and ensure compliance with Medicare's rules and regulations. See Alexander v. Azar, No. 11-cv-1703, 2020 WL 1430089, at *14 (D. Conn. Mar. 24, 2020).

In order to conduct a post-payment audit through statistical sampling, a Medicare contractor or other agent must typically select a sample of the healthcare provider's claims from the time period under review, calculate the error rate, and finally extrapolate the overpayment amount. See Gen. Med. P.C. v. Azar, 963 F.3d 516, 519 (6th Cir. 2020). This process can be broken down into six steps: (1) selecting the provider or supplier; (2) selecting the period to be reviewed; (3) defining the universe, the sampling unit, and the sampling frame; (4) designing the sampling plan and selecting the sample; (5) reviewing each of the sampling units and determining

if there was an overpayment or underpayment; and (6) estimating or projecting the overpayment. See MPIM Ch. 8 § 8.4.1.3. The MPIM instructs that, for each step, the contractor must provide documentation sufficient to explain actions taken and "to replicate, if needed, the statistical sampling." Id. The "universe" is the set of all Medicare claims submitted by the provider within a given time frame. Id. at § 8.4.3.2.1(A). The "sampling unit" is the subset of the universe which the audit is examining. Id. at § 8.4.3.2.2. An audit's parameters may filter out certain sampling units, and the remaining sampling units are the "sampling frame." Id. at § 8.4.3.2.3. The "sampling plan" is the design of the sample, of which there are several acceptable designs which Medicare contractors use, and which utilize a computer program to generate a sequence of random numbers to be matched to position numbers of sampling units in the sampling frame. Id. at § 8.4.4.1. Sampling units are then paired with random numbers to determine the portion of the sample to be audited and used for extrapolation. Id. at § 8.4.4.2.

b. Review of Post-Payment Medicare Audits

After a Medicare contractor or other agent completes their audit, the healthcare provider may challenge the audit through a multi-level appeals process. See generally 42 U.S.C. § 1395ff (summarizing steps in the appeal process). Through this process, the healthcare provider may challenge the sampling methodology. See CMS Rul. 86-1. First, the healthcare provider requests a redetermination, which is processed by a Medicare Administrative Contractor ("MAC"). See Id. at § 1395ff(a)(3). The healthcare provider may subsequently move for reconsideration by a Qualified Independent Contractor (QIC). See Id. at § 1395ff(c). The third step of the appeals process is a hearing by an Administrative Law Judge ("ALJ") at the Office of Medicare Hearings and Appeals. See Id. at § 1395ff(d)(1). An ALJ's determination is subject to *de novo* review by the Medicare Appeals Review Council (the "Council"), a component of HHS. Id.

at § 1395ff(d)(2)(B). The Council may decide to review an ALJ's decision on its own motion. 42 C.F.R. § 405.1110. However, if CMS or one of its contractors did not appear before the ALJ, the Council may only exercise own-motion review when the ALJ's decision contains a material error of law or addresses a policy or procedural issue that may affect the public interest. Id. at § 405.1110(c)(2). The Council's ruling is subject to judicial review in Federal Court. Id. at § 405.1130.

c. Appeal at Bar

In 2013, the Office of the Inspector General ("OIG") initiated an audit of Methodist's inpatient hospital billings to Medicare, issuing its final findings on October 22, 2014. (ECF No. 21-2 ¶ 4.) OIG's contractor identified 3,590 Medicare paid claims between January 10, 2011 and June 6, 2012, out of an inpatient universe of more than 15,000, to be the subject of the audit. (Id. at ¶ 5.) The contractor then selected a sample of 150 claims, found 48 overpayments, and extrapolated $5,893,302 in overpayments to Methodist. (Id. at ¶¶ 6–7.) Eight claims identified as being outside of the audit definition were found in that sampling frame, with one of those claims being selected as part of the sample. (Id. at ¶ 8.)

Methodist subsequently began the multi-level appeals process for Medicare overpayment audits. Methodist requested redetermination on March 25, 2015 by a MAC, Novitas Solutions, challenging both the OIG contractor's sampling methodology and its determinations on specific claims. (Id. at ¶ 9.) The MAC upheld the statistical sampling methodology and increased the overpayment assessment to $6,098,371. (Id. at ¶ 10.) Methodist then requested reconsideration on August 4, 2015 by Maximus Federal Services Inc., a QIC, again challenging both the OIG contractor's sampling methodology and its determinations on specific claims. (Id. at ¶ 11.) The QIC found several specific claims met Medicare coverage guidelines and modified the

overpayment assessment to $4,948,753, but still upheld the validity of the statistical sampling methodology. (Id. at ¶ 12.)

Methodist then challenged both the OIG contractor's sampling methodology and its determinations on specific claims by requesting a hearing before ALJ LaSandra Morrison. (Id. at ¶ 14.) No testimony supporting the OIG contractor's extrapolation process or the implementation of its statistical sampling methodology were submitted to that hearing on June 11, 2020, and the contractor did not appear. (Id. at ¶ 14.) In addition to finding that additional claims satisfied Medicare coverage & payment requirements, the ALJ also found that OIG's statistical extrapolation process did not comply with § 1893 of the Social Security Act, nor with the MPIM's guidance on statistical extrapolation. (Id. at ¶¶ 16–17.) The ALJ held that HHS policy requires that the OIG's audit must be able to be recreated and that as the audit's sampling frame utilized data from outside of the audit, the audit could not be recreated. (Id. at ¶ 18.)

On February 16, 2021, the Administrative Qualified Independent Contractor ("AdQIC"), acting on behalf of CMS, referred the ALJ decision to the Council for review on its own motion. (Id. at ¶ 20.) The referral was made on the basis that the ALJ relied on inappropriate grounds in finding that the statistical sampling process was invalid. (Id. at ¶ 21.) There was no challenge to the ALJ's findings regarding any individual claims. (Id.) Methodist filed exceptions on March 18, 2021, contesting the substance of the referral and arguing that the referral did not meet the standard for review by the Council. (Id. at ¶ 22.) The Council subsequently reviewed the ALJ's decision on its own motion and reversed that decision in part, finding that the ALJ's determination that the sampling process was invalid was an error of law. (Id. at ¶ 23.) The Council then concluded that the OIG contractor's statistical extrapolation met all applicable Medicare legal and regulatory requirements. (Id.)

B. Procedural Background

Plaintiff filed this action on July 19, 2021. (ECF No. 1.) Defendant filed an Answer to the Complaint on November 8, 2021. (ECF No. 18.) Plaintiff then filed the instant Motion for Summary Judgment on February 28, 2022. (ECF No. 21.) Plaintiff also filed a Memorandum of Law and a Statement of Undisputed Material Fact in support of the motion at that time. (ECF Nos. 21-1–2.) Defendant filed a Response in Opposition to the Defendant's Motion for Summary Judgment on April 15, 2022. (ECF No. 25.) Defendant also filed a Statement of Fact and Response to Plaintiff's Statement of Fact in Support at that time. (ECF Nos. 25-1–2.) Plaintiff filed a Reply to Defendant's Response in Opposition to the Defendant's Motion for Summary Judgment on May 5, 2022. (ECF No. 26.) Plaintiff filed Responses to Defendant's Statement of Material Facts on July 8, 2022. (ECF No. 29.) Defendant filed an Amended Response to Plaintiff's Statement of Facts on July 11, 2022. (ECF No. 30.)

II. LEGAL STANDARD

A. Standard of Review of Final Agency Decision

A district court reviews a final agency decision of the Secretary of the Department of Health and Human Services pursuant to 42 U.S.C § 1395ff(b)(1) (incorporating 42 U.S.C. § 405(g)). The district court's review consists of determining whether, in light of the record as a whole, the Secretary's determination is supported by "substantial evidence." Anderson v. Burwell, 167 F.Supp.3d 887, 896 (E.D. Mich. 2016). Substantial evidence is "more than a scintilla, but less than a preponderance" of relevant evidence, such "as a reasonable person would accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971). In making the determination as to whether substantial evidence exists, the court "is limited to an examination of the record only" and does not "review the evidence de novo, make credibility determinations [or]

weigh the evidence." Brainard v. Secretary of Health and Human Services, 889 F.2d 679, 681 (6th Cir. 1989) (*per curiam*). If there is substantial evidence to support the final agency decision, the decision "must be affirmed even if the reviewing court would decide the matter differently. . . and even if substantial evidence also supports the opposite conclusion." Gen. Med. P.C., 963 F.3d at 520 (citing Cutlip v. Sec'y of Health & Human Servs., 25 F.3d 284, 286 (6th Cir. 1994)) (internal citation omitted). Under 42 U.S.C. § 1395ff(b)(1)(A) (incorporating § 405(g)), the district court's powers are to "affirm[], modify[], or revers[e] the decision of the [Secretary of HHS]," and the court may remand the case for rehearing. See 42 U.S.C. § 405(g).

III. ANALYSIS

Plaintiff has amply demonstrated that the Council did not have the authority to overturn the decision of the ALJ on own-motion review. Accordingly, Plaintiff's Motion for Summary Judgement is **GRANTED**. This jurisdictional issue is discussed below.

A. The Jurisdiction of the Council

When neither CMS not its contractors have appeared in a hearing before the ALJ, as is the case in the matter at bar, the Council may only take up the matter on own-motion review if the ALJ's decision "contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest." 42 C.F.R. § 405.1110(c)(2).

Plaintiff argues that the Council lacked the authority to engage in own-motion review of the determination of the ALJ. (ECF No. 21-1 at PageID 1693.) Plaintiff asserts the ALJ's determination that the OIG contractor did not create a valid probability sample was a factual, not a legal, determination. (Id. at PageID 1696.) Defendant responds that the ALJ's determination did, in fact, contain an error of law, and that the Council therefore had jurisdiction to review this case on its own motion. (ECF No. 25 at PageID 1723.) Defendant contends that the ALJ

misapplied the MPIM in making the determination that the OIG contractor's probability sample was invalid. (ECF No. 31 at PageID 1787.) According to Defendant, misconstruing or misapplying the Medicare guidelines on sampling and extrapolation is an error of law. (ECF No. 25 at PageID 1723.)

B. Errors of Law Generally

Findings of law and errors of law are undefined by the regulation establishing the authority of the Council. See 42 C.F.R. § 405.1110. However, the "wholesale disregard, misapplication, or failure to recognize controlling precedent" has been found to be a material error of law in the context of the own-motion review of the Council. Aloi v. Azar, 337 F.Supp.3d 105, 108–9 (D.R.I. 2018). In the case at bar, the ALJ cited to "applicable MPIM requirements regarding probability sampling, as well as the CMS ruling on which Medicare sampling authority is based." (ECF No. 1-2 at PageID 135.) The ALJ therefore recognized and applied applicable guidance and precedent in finding "credible the uncontroverted testimony" of Methodist's expert witnesses. Aloi, 337 F.Supp.3d at 109.

C. The ALJ's Findings were Findings of Fact

Defendant asserts that the Council had jurisdiction to engage in own-motion review because the ALJ did not correctly apply manual guidance, and thus made an error of law. (ECF No. 31 at PageID 1783–4.) The ALJ found that the sampling frame which OIG created included "data outside of the audit" and that such a sample "cannot be re-created." (ECF No. 1-1 at PageID 27.) She therefore concluded that the OIG's execution of an otherwise acceptable methodology invalidated the extrapolation. (Id. at PageID 27.) Defendant contends that the ALJ failed to recognize that the MPIM requirements were methodological, and not based on the outcome of the statistical extrapolation. (ECF No. 31 at PageID 1783–4; see also ECF No. 25 at PageID 1730

(The "loss of a probability sample" turns upon "the method [by which] a sample is drawn." (citing ECF No. 19-2 at PageID 213.))) Defendant's position is therefore that the ALJ should have upheld the OIG's methodology because the use of the appropriate methodology meant that the inclusion of data outside of the audit "did not invalidate the probability sample." (ECF No. 31 at PageID 1795; see also ECF No. 25 at PageID 1722.)

The MPIM specifically requires that the results of an audit be repeatable and have a "known probability of selection." MPIM Ch. 8 § 8.4.2. The ALJ examined the testimony of experts and the data at hand and determined that elements of the OIG contractor's sampling unit both "cannot be re-created" and that, in this case, the number of samples was not "known." (ECF No. 1-1 at PageID 27–8.) A post-payment audit's failure to conform with the MPIM guidelines does not necessarily affect the validity of sampling or extrapolation. See Maxmed Healthcare, Inc. v. Price, 860 F.3d 335, 341 (5th Cir. 2017). Here, the ALJ made a factual finding that such shortcomings *did* impact the validity of the extrapolation. (ECF No. 1-1 at PageID 27.)

In other words, the ALJ found flaws in the execution of the adopted methodology. (Id. at PageID 27–8.) Specifically, the ALJ agreed with Methodist that "[t]he presence of claims outside of the audit definition makes it impossible to obtain a valid sample because such claims by definition should not have been available to be sampled if the audit methodology had been followed." (Id. at PageID 27.) She described an "error of this magnitude" as "contaminat[ing] the entire sampling process [and invalidating] the proposed extrapolation." (Id.) The ALJ concluded that

> [T]he presence of claims outside of the audit definition meant that claims could not randomly be sampled from a correctly constituted frame. One cannot randomly sample claims that should not be present in the frame. Given the uncertainty surrounding the stratum-one sampling frame and its composition of RAC claims this ALJ finds the sample and resulting extrapolation invalid."
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> (Id. at PageID 28.)

The Council may have disagreed with the factual findings of the ALJ, but the ALJ's findings violate no clear legal standard.

D. The ALJ's Findings Did Not Address a "Broad Policy or Procedural Issue"

In the alternative, Defendant argues that the Council did, in fact, have the authority to take up this matter on own-motion review, whether the question at hand is one of fact or of law. (See ECF No. 25 at PageID 1724.) They assert that the regulation also allows them to take up review of any "broad policy or procedural issue that may affect the general public interest." (Id.) They argue that the use of sampling and extrapolation is integral to the management of the Medicare program. (Id. at PageID 1726–27.) It is therefore essential, they maintain, that ALJs apply consistent guidelines around sampling and extrapolation, such that all matters of sampling and extrapolation implicate "broad policy or procedural issue[s]." (Id. at PageID 1727.)

The law does not define what a "broad policy or procedural issue" might be, and caselaw also offers no guidance. Defendant's argument lacks any limiting principle. The law allows for review by the Council of an ALJ's determination in a wide array of instances when CMS or its representative contractors appear at a hearing before an ALJ, but limits the Council's discretion to review when CMS or its representative contractors are not present. See 42 C.F.R. § 405.1110. This arrangement clearly contemplates that the Council would not have the sweeping power to review all of Medicare's administrative adjudications regarding audits on the basis of their comprising a "broad policy or procedural issue." Id. at § 405.1110(c)(2). Defendant's argument therefore bears little weight.

A. Prior Precedent of the Council

Defendant asserts that it is the prior precedent of the Council that ALJ decisions regarding the application of guidelines and directives on sampling and extrapolation is an error of law, not

an error of fact. (ECF No. 25 at PageID 1725.) Plaintiff replies that the cases cited by Defendant are distinguishable because "in every one [of those cases] CMS or a contractor participated in the proceedings before the ALJ," unlike in the matter at bar. (ECF No. 26 at PageID 1747 n. 2.) Plaintiff also argues that the Council was incorrect in stating that it "was not required to weigh any evidence" in making a determination regarding the application of the MPIM. (Id. at PageID 1747 n. 3.)

The Council has consistently taken matters up on own-motion review and characterized the application of CMS guidelines on sampling and extrapolation as errors of law. See, e.g., In the Case of Simon Becker, D.P.M., Docket No. M-12-1848, 2012 WL 4760809 (Medicare Appeals Council Sept. 4, 2012) at *7, aff'd Civil Action No. 12–6177, 2014 WL 2711958 (D.N.J. June 3, 2014). Nowhere does the case law indicate that every question regarding the application of the MPIM's statistical sampling and extrapolation guidelines is a matter of law. In the instance at bar, the Council saw the ALJ's determination as a legal determination, as opposed to a factual one, because the ALJ was not required to "weigh[] the evidence" in determining whether a valid probability sample exists. (ECF No. 1-2 at PageID 135.) However, it is unclear how an ALJ could determine whether or not any sample was "repeatable" or whether the contractor had utilized a "known" number of samples without weighing any evidence. MPIM Ch. 8 § 8.4.2. In the case at hand the ALJ made a factual determination, through the weighing of evidence, that the sample could not be re-created and that the number of samples was not known. (ECF No. 1-1 at PageID 27–8.) Whether or not the Council has, in reviewing cases regarding statistical sampling and extrapolation, *generally* held that such determinations are determination of law and not of fact, here the ALJ made a determination of fact.

The ALJ's findings were thus findings of fact, not of law. The Council did not have

authority to take this matter up on own-motion review. The ALJ found the facts based on the record before her and determined that the OIG conducted a fundamentally flawed statistical extrapolation.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Summary Judgment is **GRANTED**. The Council's decision is vacated and the findings of the ALJ are affirmed.

IT IS SO ORDERED, this 29th day of September, 2022.

/s/ Jon P. McCalla
JON P. McCALLA
UNITED STATES DISTRICT JUDGE